EVALUATION OF THE CERTIFICATE OF NEED APPLICATION SUBMITTED ON BEHALF OF OLYMPIC PENINSULA KIDNEY CENTER, INC. PROPOSING TO AMEND CERTIFICATE OF NEED #1307 DUE TO A CHANGE IN THE APPROVED SITE

PROJECT DESCRIPTION

On June 3, 2005, Olympic Peninsula Kidney Center (OPKC) was issued Certificate of Need (CN) #1307 approving the establishment of an eight station dialysis center in the city of Poulsbo, within Kitsap County. The new dialysis center, known as OPKC-North Kitsap, was to be located in the Powder Hill Business Center Complex, specifically at 19462 Powder Hill Place in Poulsbo. During the course of implementing CN #1307, OPKC elected to relocate the dialysis center to another building within the Powder Hill Business Complex, specifically at 19472 Powder Hill Place. [source: CN historical files and Progress Reports filed for CN #1307]

This application proposes to amend CN #1307 because of a change in the approved site to a new site within the same complex. CN #1307 was issued with an approved capital expenditure of \$921,703. The change in the site for the dialysis center does not affect the costs of the project, nor does it affect any other portions of the approved project.

APPLICABILITY OF CERTIFICATE OF NEED LAW

This project is subject to CN review under Revised Code of Washington (RCW) 70.38.105(4)(a) and WAC 246-310-570(1)(f) because the approved site for the project authorized by CN #1307 has changed.

APPLICATION CHRONOLOGY

ATTEICATION CHRON	OLOG1
June 20, 2005	Letter of Intent submitted
August 18, 2005	Application submitted ³
August 19, 2005 through	Applicant requests no action on the application until completion of a
January 5, 2006	judicial appeal related to the issuance of CN #1307
January 6, 2006	Applicant requests department resume action on application
January 9, 2006	Application assigned to analyst
January 10, 2006	Department's Pre-Review Activities
through April 2, 2006	• 1 st screening activities and responses
April 3, 2006	Applicant withdraws request for additional stations and requests to amend
	CN #1307 because of a change in approved site
April 7, 2006	Department Begins Review of the Amendment Application
	 public comments accepted throughout review
	Reviewed under expedited review timeline; no public hearing conducted
April 27, 2006	End of Public Comment

¹ CN #1307 was issued consistent with the February 28, 2005, <u>Findings of Fact, Conclusions of Law, and Final Order</u> and the May 26, 2005, <u>Amended Findings of Fact, Conclusions of Law, and Final Order</u> both issued by the Adjudicative Service Unit Health Law Judge.

² This evaluation acknowledges that CN #1307 was issued with a typographical error for the site address; CN #1307 inadvertently identified the site to be 19642 Powder Hill Place, rather than 19462 Powder Hill Place.

³ OPKC initially submitted this application to add five dialysis stations to OPKC-North Kitsap.

APPLICATION CHRONOLOGY (continued)

May 12, 2006	Rebuttal Documents Submitted to Department ⁴
June 1, 2006	Department's Anticipated Decision Date
May 9, 2006	Department's Actual Decision Date

AFFECTED PARTIES

Throughout the review of this project, one entity sought and received affected person status as defined in WAC 246-310-010:

• DaVita, Inc. a dialysis provider in Washington State

SOURCE INFORMATION REVIEWED

- Olympic Peninsula Kidney Center's Certificate of Need Application submitted August 18, 2005
- Olympic Peninsula Kidney Center's supplemental information dated April 3, 2006, and April 14, 2006
- Licensing and/or survey data provided by the Department of Health's Office of Health Care Survey
- Certificate of Need historical files

CRITERIA EVALUATION

The review for an amendment project is limited to only those criteria that would be affected by the amendment, provided that the amendment does not alter the basic justification for the initial approval. Based on information presented in this amendment application, the relocation of the dialysis center does not alter the initial justification for the approval of the project. Therefore, to obtain CN approval for this project, Olympia Peninsula Kidney Center must demonstrate compliance with the relevant criteria found in 246-310-220 (financial feasibility); 246-310-230 (structure and process of care); and 246-310-240 (cost containment).⁵

CONCLUSION

For the reasons stated in this evaluation, the Olympic Peninsula Kidney Center proposal to relocate the approved 8-station dialysis facility, to be known as OPKC-North Kitsap, to a new site at 19472 Powder Hill Place in the city of Poulsbo, within Kitsap County is consistent with applicable criteria of the Certificate of Need Program. An amended Certificate of Need shall be issued. The expiration date of the amended Certificate of Need shall remain June 3, 2007.

The estimated capital expenditure associated with CN #1307 is \$921,703. There is no change in the capital costs associated within the change in site. The approved estimated capital expenditure for this project remains at \$921,703.

⁴ Given that no public comment was recevied regarding this project, rebuttal comments were not submitted.

⁵ Each criterion contains certain sub-criteria. The following criterion and sub-criteria are not discussed in this evaluation because they are not relevant to this amendment project: WAC 246-310-210 [need]; and WAC 246-310-240 [cost containment] (2) and (3).

A. Financial Feasibility (WAC 246-310-220)

Based on the source information reviewed, the department determines that the applicant has met the financial feasibility criteria in WAC 246-310-220.

(1) The immediate and long-range capital and operating costs of the project can be met.

In its May 21 2004, evaluation supporting the issuance of CN #1307, the department concluded that this sub-criterion was met based on the following factors:

- 1) the project would be financed through OPKC reserves;
- 2) a review of OPKC's historical audited financial report; and
- 3) a review of the proposed dialysis center's projected patient utilization, including proposed revenues, expenses, and net profit.

The department's review of the initial project concluded that OPKC had the funds to finance the project through its reserves, and the dialysis center would be able to meet its immediate and long-range capital and operating costs of the project.

In the initial application, OPKC provided a copy of the draft lease agreement for the initial site. The draft agreement was scheduled to commence June 2004 and extended for ten years. Annual cost for the 4,994 sf site was identified at \$20/sf, or \$99,880, which equated to a monthly cost of approximately \$8,323. Within the amendment application, OPKC provided a copy of the executed lease agreement for the new site. The agreement, which commenced on October 1, 2005, also extends for ten years. The agreement was signed by all parties on August 2, 2005, and identifies all costs associated with the lease of the space, and roles and responsibilities of all parties. The new space, at 5,585 sf, is slightly larger than the initial space, resulting in an increase in lease costs. The new site identifies an annual cost of \$19/sf, which equates to an annual cost of \$105,280 or \$8,773/month. The lease costs for the new site are identified in the revised pro forma financial statements provided by the applicant.

The change in the site does not change the capital expenditure for the project. A second review of OPKC's historical financial data and the proposed dialysis center's projected income statements and balance sheets, reveals that OPKC continues to have the funds to finance the project through its reserves, and the dialysis center would be able to meet its immediate and long-range capital and operating costs of the project. This sub-criterion remains met.

(2) <u>The costs of the project, including any construction costs, will probably not result in an unreasonable impact on the costs and charges for health services.</u>

In the initial evaluation, the department compared the dialysis center's proposed costs and charges to the average costs and charges of existing dialysis centers and concluded that they are reasonable. Within the amended application, there was no additional information provided that would change this conclusion. [source: CN historical files]

Based on the information provided above, the department concludes that the cost of the project identified in the amended application will not result in an unreasonable impact on the costs and charges for health services within the service area. This sub-criterion is met.

(3) The project can be appropriately financed.

The approved capital expenditure associated with CN #1307 authorizing the establishment of the 8-station dialysis center is \$921,703. In the initial application, OPKC stated it will use reserves (board designated assets) to finance this project. To evaluate whether OPKC had the funding for the project in the initial review, staff reviewed OPKC's most recent audited financial report. After reviewing the financial report, staff concluded that the project could be appropriately financed.

In this amendment application, the applicant provided documentation demonstrating that the change in the approved site does not affect the capital expenditure for this project. As a result, within the amendment application, there is no additional information provided that would change the department conclusion regarding this sub-criterion, the department again concludes that the proposed financing is appropriate and this sub-criterion is met.

B. Structure and Process (Quality) of Care (WAC 246-310-230)

Based on the source information reviewed, the department determines that the applicant has met the structure and process (quality) of care criteria in WAC 246-310-230.

- (1) <u>A sufficient supply of qualified staff for the project, including both health personnel and management personnel, are available or can be recruited.</u>
 - In its May 24, 2004, evaluation, the department concluded that a sufficient supply of qualified staff would be available or recruited to staff the 8-station dialysis center. Within the amended application, there was no additional information provided that would change this conclusion regarding this subcriterion. Therefore, the department concludes that this criterion is met.
- (2) <u>The proposed service(s)</u> will have an appropriate relationship, including organizational relationship, to ancillary and support services, and ancillary and support services will be sufficient to support any health services included in the proposed project.
 - In the initial application, there were several contracts and ancillary agreements provided for the department's review. In its May 21, 2004, evaluation, the department recognized OPKC as an existing provider of dialysis services in the county, and recognized that the OPKC already had appropriate relationships with all necessary ancillary and support services needed for its existing dialysis centers. For the new dialysis center in north Kitsap County, the department recognized that many of the existing agreements would incorporate the new center by reference. Within the amended application, there was no additional information provided that would change this conclusion. This sub-criterion remains met.
- (3) There is reasonable assurance that the project will be in conformance with applicable state licensing requirements and, if the applicant is or plans to be certified under the Medicaid or Medicare program, with the applicable conditions of participation related to those programs.
 - In its May 21, 2004, evaluation, the department concluded that OPKC would continue to operate its existing dialysis centers in conformance with applicable state and federal licensing and certification requirements. Further the department concluded that the addition of a new OPKC dialysis center in Kitsap County would not negatively affect OPKC's historical quality of care. Within the amended application, there was no additional information provided that would change this conclusion. Therefore, the department concludes that this criterion is met.

(4) The proposed project will promote continuity in the provision of health care, not result in an unwarranted fragmentation of services, and have an appropriate relationship to the service area's existing health care system.

In its May 21, 2004, evaluation, the department concluded that the project would promote continuity in the provision of health care with the existing providers in the community. Changing the location of the dialysis center within the same complex as the existing site does not change the department's conclusion regarding this criterion. This sub-criterion remains met.

(5) <u>There is reasonable assurance that the services to be provided through the proposed project will be provided in a manner that ensures safe and adequate care to the public to be served and in accord with applicable federal and state laws, rules, and regulations.</u>

This sub-criterion is addressed in sub-section (3) above and is considered met.

C. Cost Containment (WAC 246-310-240)

Based on the source information reviewed, the department determines that the applicant has met the cost containment criteria in WAC 246-310-240.

(1) <u>Superior alternatives, in terms of cost, efficiency, or effectiveness, are not available or practicable</u>. In its May 21, 2004, initial evaluation, the department concluded that the OPKC project was not the best option for the community, resulting in a denial of the OPKC project and an approval of the competing DaVita application reviewed comparatively with OPKC's application. On February 25, 2005, and May 26, 2005, the Department of Health's Adjudicative Services Unit issued its initial and amended <u>Findings of Fact, Conclusions of Law and Final Order</u>. Within that document, the Health Law Judge (HLJ) reversed the department's decision, instead concluding that OPKC, not DaVita, was the best alternative for the community. As a result, the department's May 21, 2004, initial evaluation does not support a conclusion that OPKC is the best alternative, however, the initial and amended decisions by the HLJ do support this conclusion.

As stated in the project description portion of this evaluation, the change in site to a building in the same complex does not affect the approved cost of the project. Based on the information provided in the amendment application and the rationale for the change in site, the department maintains that the establishment of OPKC's 8-station dialysis center in Poulsbo continues to be the best available option for the community based on the HLJ's initial and amended <u>Findings of Fact, Conclusions of Law and Final Order</u>. The department further concludes that submission of this amendment application is consistent with the rules regarding amendment applications. [source: CN historical files] This subcriterion is met.

(2) In the case of a project involving construction:

(a) <u>The costs, scope, and methods of construction and energy conservation are reasonable; and</u>
In the initial evaluation for this project, the department acknowledged that the majority of the capital expenditure for OPKC's new 8-station dialysis center is related to remodeling leased space and the purchase of additional fixed and moveable equipment. The construction costs are reasonable when compared to construction costs of recent kidney dialysis proposals. Within the amended application, there was no additional information provided that would change this conclusion. Therefore, the department concludes that this criterion is met.

(b) The project will not have an unreasonable impact on the costs and charges to the public of providing health services by other persons.

This sub-criterion is re-evaluated within the financial feasibility criterion under WAC 246-310-220(2) and is considered met.